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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,657	11/26/2003	Mark B. Dominick	136092SV/YOD GEMS:0244	7668

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EXAMINER	
SQUIRES, ELIZA A	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
12/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,657	DOMINICK ET AL.	
	Examiner	Art Unit	
	Eliza Squires	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-16,19,20,22 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 6-16, 19-20, 22, and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment dated 10/6/2009 has been entered. Claims 1, 6, 12, and 15 have been amended. Claims 1-, 6-16, 19-20, 22, and 24 are currently pending in the application.

Response to Arguments

2. Applicant's arguments filed 10/6/2009 have been fully considered but they are not persuasive.

Rejections under 35 USC 112

3. The rejections under 35 USC 112 have been withdrawn in light of Applicant's amendment.

Rejections under 35 USC 103

4. Applicant argues on page 9 and 10 that *Kaseya* does not teach "wherein the medical device is operable to detect an alteration of at least one of medical device hardware and medical device software by a service provider." *Kaseya* teaches "Get instant notification when:...a user removes an application". Applicant does not provide a special definition of a "service provider", Examiner defines the term as "a person who performs a service on a device". The user of *Kaseya* fits this description as the user adds and removes hardware or software on the device. As a "service provider" is analogous to a "user", the rejection is maintained.

5. Applicant argues that the references do not teach "operating the computer system to generate a service report based on a combination of the medical device data and the service provider data." Both the medical device data and the service provider data in the claims are data related to a change in hardware or software. *Kaseya* teaches "Get instant notification when:...a user removes an application". As discussed above, a "service provider" is analogous to "a user".

Additionally, a notification is considered a report (a service report) which contains a combination of the medical device data and service provider data (notification when a user installs a new application). The reference therefore teaches the limitation and the rejection is maintained.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 1, 6, 11-16, and 19-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of *Kaseya*.

8. **As to claim 1,** *Yokoi* discloses a method for producing a service report for a service performed on a medical device by a service provider, comprising:

operating a computer system to receive medical device data transmitted to the computer system from a medical device via a communications network (abstract and column 3 lines 18-27 and column 4 lines 19-47);

operating the computer system to receive service provider data transmitted automatically to the computer system via the communications network, wherein the service provider data comprises information related to the service performed on the medical device (abstract and column 3 lines 18-27, column 3 lines 45-61, and column 4 lines 19-47); and

However, *Yokoi* does not explicitly teach that the medical device is operable to detect an alteration of hardware or software and this information is transmitted automatically. *Kaseya* discloses:

wherein a computer is operable to detect an alteration of hardware, and wherein the data transmitted automatically by the medical device is representative of the alteration by the service provider and operating the computer system to generate a service report based on the medical device data and the service provider data (*Kaseya* pages 1 and 2 see "instant notification when:.. a user removes or adds a PCI card).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the reporting system of *Yokoi* with the inclusion of the automatic detection system of *Kaseya* in order to ensure the existence of the correct operational parameters within a medical device (*Yokoi* column 8 lines 26-38).

9. **As to claim 6,** *Yokoi* discloses a method for facilitating the preparation of a service report for a medical device; comprising:

providing medical device service data automatically from the medical device to a computer system via a communications network (abstract and column 3 lines 18-27 and column 4 lines 19-47);

providing service provider data automatically to the computer system via a communications network, wherein the service provider data comprises information related to the service performed on the medical device (abstract and column 3 lines 18-27, column 3 lines 45-61, and column 4 lines 19-47); and

However, *Yokoi* does not explicitly teach that the medical device is operable to detect an alteration of hardware or software and this information is transmitted automatically. *Kaseya* discloses:

wherein the medical device is operable to detect an alteration of medical device hardware and wherein the medical device data transmitted automatically by the medical device is representative of the alteration and generating a service report based on the service data and the service provider data automatically using the computer system (pages 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the reporting system of *Yokoi* with the inclusion of the automatic detection

system of *Kaseya* in order to ensure the existence of the correct operational parameters within a medical device (*Yokoi* column 8 lines 26-38).

10. **As to claim 11,** see the discussion of claim 6, additionally, *Yokoi* discloses the method comprising transmitting the service report from the computer system to a remote device to enable a user to revise the service report (column 6, lines 6-19).

11. **With respect to claim 12,** *Yokoi* discloses a medical information system, comprising:

a medical device comprising hardware and software, the medical device being operable to communicate with a remote computer via a communication system (column 3, lines 46-58).

However *Yokoi* does not disclose that the device is operable to detect a change in hardware and software. *Kaseya* discloses that the system is operable to detect a change in each of the hardware and the software, wherein the change in software comprises a software upgrade and to automatically transmit a signal representative of the change to the remote computer (*Kaswya* page 2 "Get instant notification when:…a user installs a new application…a user removes or adds a PCI card").

12. **With respect to claim 13,** see the discussion of claim 12, additionally, *Yokoi* discloses the medical information system wherein the medical device is a medical imaging system (column 1, lines 12-22).

13. **As to claim 14,** see the discussion of claim 12, additionally, *Yokoi* discloses the medical information system as recited in claims 12, wherein the communication system comprises a network (column 4, lines 42-47).

14. **As to claim 15,** *Yokoi* discloses a processor based system comprising:

machine-executable programming instructions physically stored in the processor based system,

wherein the programming instructions enable a processor-based device to produce a service report for a medical device based on medical device data received automatically from the medical device and service provider data received automatically from a remote device (abstract, column 3 lines 18-27 and column 4 lines 19-47, and figure 2).

However, *Yokoi* does not explicitly teach that the medical device is operable to detect an alteration of hardware or software and this information is transmitted automatically. *Kaseya* discloses:

wherein the medical device is operable to detect an alteration of at least one of medical device hardware and wherein the medical device data transmitted automatically by the medical device is representative of the alteration and generating a service report based on the service data and the service provider data automatically using the computer system (pages 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the reporting system of *Yokoi* with the inclusion of the automatic detection system of *Kaseya* in order to ensure the existence of the correct operational parameters within a medical device (*Yokoi* column 8 lines 26-38).

15. **As to claim 16,** see the discussion of claim 15, additionally, *Yokoi* discloses the processor based system wherein the programming instructions enable the processor-based device to produce a service report containing data representative of at least one of a hardware and a software change to the medical device (column 3 lines 18-27 and column 4 lines 19-47, and figure 2).

16. **As to claim 19,** see the discussion of claim 15, additionally, *Yokoi* discloses the processor based system wherein the system enables a user to use the remote device to revise the service

report and to transmit the revised service report to the computer system via the network (column 6, lines 6-19).

17. **As to claim 20,** see the discussion of claim 1, additionally, *Yokoi* discloses the method comprising operating the computer system to communicate the service report to a parts database via the communication network (*Yokoi* column 7 lines 39-67).

18. **As to claim 22,** see the discussion of claim 1, additionally, *Kaseya* discloses the method wherein the medical device data comprises an inventory of software and hardware in the medical device (*Kaseya* page 1).

19. **As to claim 24,** see the discussion of claim 1 and 12, additionally, *Kaseya* discloses the system wherein the signal representative of the change is automatically transmitted to the remote computer (*Kaseya* pages 1 and 2).

20. **Claims 2 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of *Kaseya* in further view of *Krasner*.

21. **As to claim 2,** see the discussion of claim 1, however, *Yokoi* and *Kaseya* do not explicitly disclose the tracking of a service provider. *Krasner* discloses the method wherein the service provider data comprises GPS location data from a remote device transported by the service provider (column 22, lines 41-67 and column 23, lines 1-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* and *Kaseya* with *Krasner* in order to more accurately locate and verify the location of personnel to better confirm that the service was truly rendered.

22. **As to claim 9,** see the discussion of claim 6, additionally, *Yokoi* discloses a service report (column 3, lines 14-26 and column 4 lines 42-47). However, *Yokoi* does not explicitly disclose the tracking of a service provider. *Krasner* discloses the method wherein the service provider data comprises GPS location data for the service provider (column 22, lines 41-67 and column 23, lines 1-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Krasner* in order to more accurately locate, verify and document the location of personnel to better confirm that the service was truly rendered.

23. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of *Kaseya* in further view of the manual published by the *FDA* last revised 1/1/97 entitled "Quality System Manual".

24. **As to claim 7,** see the discussion of claim 6, however, *Yokoi* and *Kaseya* do not disclose that the service report comprises a list of services performed. *FDA* discloses the method wherein the service report comprises a listing of services performed by the service provider based on the service provider data (service reports section, page 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* and *Kaseya* with *FDA* in order to comply with governing body regulations for contents of a service report.

25. **Claims 8 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of *Kaseya* in further view of "Reliable Design of Medical Devices" by *Richard C. Fries*.

26. **As to claim 8,** see the discussion of claim 6, however, *Yokoi* and *Kaseya* do not explicitly disclose that a listing of parts is included in the service report. *Fries* discloses the method wherein the service report comprises a listing of parts replaced by the service provider based on the service data (section 28.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* and *Kaseya* with *Fries* to provide data for a meaningful analysis of product reliability as disclosed by *Fries* (section 28.1).

27. **As to claim 10,** see the discussion of claim 6, however, *Yokoi* and *Kaseya* do not explicitly disclose time keeping data as a service record component. *Fries* discloses the method wherein the service report comprises service time data for the service provider (section 28.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* and *Kaseya* with *Fries* to provide data for a meaningful analysis of product reliability as disclosed by *Fries* (section 28.1).

Conclusion

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliza Squires whose telephone number is (571)270-7052. The examiner can normally be reached on Monday through Friday 8 am - 4 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. S./
Examiner, Art Unit 3626
12/18/2009
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